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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,129	06/24/2003	David J. Schuessler	33915-03420	9875
7590 09/30/2004 Christopher E. Chalsen Milbank, Tweed, Hadley & McCloy, LLP One Chase Manhattan Plaza New York, NY 10005			EXAMINER NOLAN, SANDRA M	
			ART UNIT 1772	PAPER NUMBER

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/603,129	<b>Applicant(s)</b> SCHUESSLER, DAVID J.	
	<b>Examiner</b> Sandra M. Nolan	<b>Art Unit</b> 1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 23-44 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10-1-03</u> . | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Claims***

1. Claims 23-44 are pending. Claims 1-22 have been cancelled.

### ***Information Disclosure Statement***

2. The information disclosure statement (IDS) submitted on 01 October 2003 was considered by the examiner.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claim 23 is rejected under 35 U.S.C. 102(b) as being anticipated by Cumer et al (US 5,665,069).

Cumer teaches rotational molding (col. 4, line 33) to make silicone syringes (col. 4, lines 38 and 35, respectively). The syringes have inner cavities (Figure 7).

The number of axes in the molding device does not affect the patentability of the articles made therewith.

5. Claims 23, 35 and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by Shah (US 6,291,543, filed 24 May 2000).

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Shah teaches catheters (col. 2, line 43) made by rotomolding (col. 5, lines 31-32) compositions containing silicones (col. 3, lines 60-61) or polyurethanes (col. 3, line 44). Catheters are well known to have cavities in them.

The number of axes in the molding device does not affect the patentability of the articles made therewith.

6. Claims 23, 35 and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by O'Hara (US 6,231,547).

O'Hara shows catheters (title) made by rotomolding (col. 7, line 67) polyurethanes or silicones (col. 7, lines 58-59). Catheters are well known to have cavities in them.

The number of axes in the molding device does not affect the patentability of the articles made therewith.

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 23 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Hara in view of Yoshino (US 5,519,082).

O'Hara is discussed above. It fails to teach silicones and platinum catalysts.

Yoshino teaches the production of medical instruments (col. 1, line 16) from compositions containing silicone rubber and a platinum catalyst (abstract).

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The patents are analogous because they both deal with silicone moldings.

It would have been obvious to one having ordinary skill in the art at the time that the invention was made to employ the silicone compositions of Yoshino to make the catheters of O'Hara.

The motivation to employ the Yoshino compositions is found at col. 1, line 16 of Yoshino, where the use of its compositions to make medical instruments is disclosed.

It is deemed desirable to make catheters from silicone rubbers so that they will be resilient.

9. Claims 23, 35 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Hara in view of Revis (US 5,091,445).

O'Hara is discussed above. It fails to teach silicones and tin catalysts.

Revis teaches silicone compositions that employ tin catalysts and are used to make penile prostheses (col. 1, lines 36-45). The compositions cure at room temperature (col. 1, lines 36-38).

The patents are analogous because they both deal with silicone moldings.

It would have been obvious to one having ordinary skill in the art at the time that the invention was made to employ the silicone compositions of Revis to make the catheters of O'Hara in order to produce them at room temperature.

The motivation to employ the silicone compositions of Revis to make the catheters of O'Hara is found at col. 1, lines 36-38 of Revis, where the room temperature curing of its compositions is taught.

It is deemed desirable to make articles at room temperature in order to lower the energy requirements of manufacturing.

### ***Nonstatutory Double Patenting***

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 39-44 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23-38 of copending Application No. 10/603904. Although the conflicting claims are not identical, they are not patentably distinct from each other because silicone and polyurethane compositions recited in the claims are conventional in the medical arts, as shown by the section 102 and 103 rejections above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Statutory Double Patenting***

12. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to

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identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

13. Claims 23-38 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 23-38 of copending Application No. 10/603904.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

### **Conclusion**

Any inquiry concerning this communication should be addressed to Sandra M. Nolan, at telephone number 571/272-1495. She can normally be reached Monday through Thursday, from 6:30 am to 4:00 pm, Eastern Time.

If attempts to reach the examiner are unsuccessful, her supervisor, Harold Pyon, can be reached at 571/272-1498.

The fax number for patent application documents is 703/872-9306.



S. M. Nolan  
Primary Examiner  
Technology Center 1700

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